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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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|-----------------|-------------|----------------------|---------------------|------------------|

10/575,311

04/11/2006

Nicola Anne Burgess

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10/16/2008

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EXAMINER

HALVORSON, MARK

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

10/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/575,311 | Applicant(s) BURGESS, NICOLA ANNE | |
| | Examiner Mark Halvorson | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 9, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 9, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Art Unit location and Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1642, Examiner Mark Halvorson.

Claims 7, 9, 28 and 29 are pending and under examination.

35 USC § 112 1st paragraph rejection maintained

The rejection of claims 7, 9, 28 and 29 for failing to comply with the enablement requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The claims are broadly drawn to a method for the treatment and/or prophylaxis of ovarian cancer comprising administering a therapeutically effective amount of an agent which interacts with or modulates the expression or activity of a CDCP1 polypeptide

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wherein the agent is an antibody, functionally-active fragment, derivative or analogue thereof wherein the antibody is monoclonal, polyclonal, chimeric, humanized or bispecific, or is conjugated to a therapeutic moiety, detectable label, second antibody or a fragment thereof, an effector or reporter molecule, a cytotoxic agent or cytokine. The claims are also broadly drawn to a method for the treatment and/or prophylaxis of ovarian cancer comprising administering a therapeutically effective amount of a composition comprising a CDCP1 polypeptide wherein the polypeptide comprises the amino acid sequence of SEQ ID No. 1 or is a derivative having one or more amino acid substitutions, modifications, deletions or insertions relative to the amino acid sequence of SEQ ID No. 1 which retains the activity of the CDCP1 polypeptide.

The specification discloses a polyclonal antibody that recognizes and binds to the CDCP1 polypeptide in ovarian cancer cells (page 35 example 4 and table top of page 36). The specification discloses internalization of the antibody/polypeptide complex 2 hours after binding (page 37). The specification does not disclose whether binding and/or internalization of the antibody/polypeptide complex leads to cell death. The specification does not disclose any *in vivo* data on the ability of the antibody to CDCP1 to treat ovarian cancer. Applicants have submitted an affidavit disclosing that an antibody to CDCP1 was effective *in vivo* using a melanoma cell line transfected with CDCP1.

Applicants arguments and Declarations have been considered but are not persuasive. The art of treating cancer is a highly unpredictable area, As such more guidance is required than other areas. Although *in vivo* data is not required it is one factor to consider and is especially relevant in highly unpredictable areas. As previously indicated, melanoma is very different disease compared to ovarian cancer, with different etiologies and different treatments. The animal model used by Applicants is not an art accepted animal model for ovarian cancer. Furthermore, the model described in Applicants Declarations used a melanoma cell line transfected with CDCP1. Thus, the concentration of CDCP1 expressed in these melanoma cells may be significantly higher than on ovarian cancer cells. In addition, the specification does not provide adequate support to enable a method of treating ovarian cancer.

Applicants also argue that an antibody fragment would be expected to successfully treat ovarian cancer if a full length antibody is successful. However, there are many properties of a full length antibody, such as ADCC and CDC, that an antibody fragment would not possess. Furthermore, antibody fragment includes Fab' fragments which would not crosslink CDCP1 receptor on the surface of the cell and may not be functional.

Given the disclosure of the specification and the teaching in the art that indicates the unpredictability of treating cancer, one skilled in the art could not predictably treat ovarian cancer comprising administering an antibody which specifically interacts with a CDCP1 polypeptide. Therefore, in view of the breadth of the claims, lack of guidance in the specification, the absence of working examples, and the state of the art, it would require undue experimentation for one skilled in the art to practice the invention as broadly claimed.

35 USC § 102(b) rejections withdrawn

The rejection of claims 7, 9 and 29 under 35 USC 102(b) as being anticipated by Schweifer et al is withdrawn in view of Applicants arguments that the disclosure in Schweifer et al does not enable a method to treat ovarian cancer.

Summary

Claims 7, 9, 28 and 29 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson
Patent Examiner
571-272-6539

/MISOOK YU/
Primary Examiner, Art Unit 1642